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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/647,243 | 08/26/2003 | Jean-Christophe Leroux | 017753-165 | 1768 |

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| EXAMINER | |
|---|---|
| TSAY, MARSHA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/647,243 | LEROUX ET AL. | |
| | Examiner | Art Unit | |
| | Marsha M. Tsay | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-24,26 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,14-18,22-24,26 and 29* is/are rejected.

7)☒ Claim(s) *9,13,19-21,30 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 2, 25, 27-28 have been canceled. Claims 29-31 are new. Claims 1, 3-24, 26, 29-31 are pending and under examination.

Priority date is August 26, 2002.

### Withdrawal of Objections and Rejections

The objection to the specification because of outdated priority information is withdrawn.

The rejection of claims 1-4, 10, 14, 16-17, 22-23, 25-28 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

### Maintenance of Rejections/New Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10-12, 14-18, 22-24 are rejected again under 35 U.S.C. 102(b) as being anticipated by Tarantino (WO 9408623). Claims 26, 29 are also rejected under 35 U.S.C. 102(b) as being anticipated by Tarantino (WO 9408623). Tarantino teaches lecithin gels are formed in vivo by absorption of water from the aqueous interstitial fluid at the injection site (p. 2, lines 1-3). Tarantino teaches the injectable pharmaceutical

composition which forms a lecithin gel in vivo for the sustained release of a biologically active compound to comprise of: 1) a pharmaceutically acceptable organic solvent which is not substantially soluble in water and which is capable of dispersing a lecithin and forming a lecithin gel upon the absorption of body fluids; 2) a biologically active compound; and 3) a lecithin dispersed in the organic solvent in an amount sufficient to cause gelation upon the absorption of body fluids (p. 3, lines 1-13; claims 1, 3). Tarantino teaches the term "lecithin" to encompass a complex mixture of acetone-insoluble phosphatides which consists chiefly of phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine, etc., combined with various substances such as triglycerides, fatty acids, and carbohydrates (p. 3, lines 25-30). The composition can also contain additional substances that further stabilize the active ingredient (p. 5, lines 21-28) or comprise excipients which act to modify the properties of the lecithin gel (p. 6). Tarantino teaches an injectable composition (example 1a) containing 0.148 mL Interferon $\alpha$-2a; 0.052 mL ammonium acetate pH 5.0; 6.0 g lecithin; and 14.8 g medium chain triglycerides (MCT) (p. 10, example 1; claims 1, 3, 6-8, 14-18). Tarantino teaches the MCT to comprise of fractionated coconut oil fatty acids $C_8$-$C_{10}$ which contains 50-65% caprylic acid and 30-45% capric acid, etc. (p. 5, lines 7-10; claims 10-12). On page 9, Tarantino teaches a solvent method for preparing injectable compositions comprising adding the bioactive ingredient to a mixture comprising lecithin and excipients in hexane (p. 9, lines 20-25; claim 26).

Tarantino teaches the subcutaneous administration of a composition containing IFN-$\alpha$, which gels upon injection, to rats (p. 14, lines 5-7; claims 23-24, 29). In Figure 1,

Tarantino demonstrates that the sustained release composition of example 1a provided detectable serum levels for at least 96 hours (p. 14, lines 24-26), indicating the organogel is in a stable gel form (claim 22, 29).

Tarantino teaches a process for preparing an injectable composition that can form a gel in vivo by intramuscular or subcutaneous injection into an animal body. Tarantino teaches that if the active ingredient is not readily dispersible in the lecithin/solvent mixture, the active ingredient may first be dissolved in a small amount of water or in a buffer solution (p. 7, lines 10-14; claim 26).

Although Tarantino does not teach the transition temperature of the organogel from the liquid state to the gel state, this property is inherent to the lecithin gels and meets the limitations of claims 4-5 because the lecithin organogel that Tarantino teaches, meets the limitations of claim 1, and changes from the liquid to the gel state upon injection into an animal body (p. 14, example 2).

To overcome the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Tarantino, Applicants have canceled claim 2 and introduced the subject matter of that claim into claim 1. However, upon reconsideration, the currently amended claim 1 is again rejected under 35 U.S.C. 102(b) as being anticipated by Tarantino (WO 9408623). As currently written, claim 1 is still drawn to a composition in liquid form which changes to the organogel form during its administration to an animal body. Although Applicants have introduced the limitation of cooling the site of application of said composition into claim 1, this is an intended use or purpose of the composition.

Claim 1 is still drawn to a composition which changes to the organogel during its administration to an animal body, and therefore as explained above, is anticipated by the Tarantino reference. In addition, on page 7 of the specification, Applicants disclose, "if necessary, the gelation of the liquid composition is induced by cooling the site of application of the composition...(p. 7, line 5). Therefore, the limitation of cooling the application site is not critical and the absence of this step will not necessarily prevent the liquid composition from changing to the organogel form.

Claims 9, 13, 19-21, 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 16, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER